

**Claims:**

- 1) A particulate composition comprising;
  - a) at least 50% of at least one structure forming amphiphile,
  - b) 0 to 40% of at least one structure swelling amphiphile, and
  - c) 2 to 20% of at least one dispersion stabilising polymeric amphiphile,

wherein all parts are by weight relative to the sum of the weights of a+b+c and wherein the composition comprises non-lamellar particles or forms non-lamellar particles when contacted with an aqueous fluid and wherein if component b) is 0% then component a) comprises at least two structure forming amphiphiles.
- 2) A particulate composition as claimed in claim 1, said composition comprising;
  - a) at least 50% of at least one structure forming amphiphile,
  - b) 2 to 40% of at least one structure swelling amphiphile, and
  - c) 2 to 20% of at least one dispersion stabilising polymeric amphiphile,

wherein all parts are by weight relative to the sum of the weights of a+b+c and wherein the composition comprises non-lamellar particles or forms non-lamellar particles when contacted with an aqueous fluid.
- 3) A composition as claimed in claim 1 or claim 2 wherein the amphiphilic components comprise at least 50% by weight amphiphiles having an aqueous solubility of less than  $10^{-9}$  M at 25°C, relative to the total weight of components a+b+c.
- 4) A composition as claimed in claim 1 or claim 2 wherein the amphiphilic components comprise at least 70%, by weight amphiphiles having an aqueous solubility of less than  $10^{-9}$  M at 25°C, relative to the total weight of components a+b+c.
- 5) A composition as claimed in any of claims 1 to 4 wherein component a) comprises at least one lipid component selected from phospholipids, glycolipids,

-28-

and diglycerides.

- 6) A composition as claimed in any of claims 1 to 5 wherein component b) comprises at least one swelling agent selected from polyoxyethylene alkylethers, polyoxyethylene sorbitan fatty acid esters, polyoxyethylene fatty acid esters, polyoxyethylene castor oil derivateives or polyoxyethylene lipid derivatives.
- 7) A composition as claimed in any of claims 1 to 6 wherein component c) comprises at least one polymeric agent selected from poloxamers, PEG-glyceroldioleate, PEG fatty acid esters or PEG-phospholipids.
- 8) A composition as claimed in any of claims 1 to 7 wherein said non-lamellar particles comprise  $L_3$  phase and/or reversed hexagonal phase.
- 9) A composition as claimed in any of claims 1 to 8 additionally comprising at least one active agent.
- 10) A composition as claimed in any of claims 1 to 9 wherein component a) comprises a cationic lipid at a level of 1-10% by weight and the composition further comprises at least one nucleic acid active agent.
- 11) A composition as claimed in any of claims 1 to 10 wherein said non-lamellar particles have a particle size of 10 to 200  $\mu\text{m}$ .
- 12) A composition as claimed in any of claims 1 to 11 wherein said non-lamellar particles are colloidal.
- 13) A composition as claimed in claim 12 wherein said non-lamellar particles are stable, both in terms of phase behaviour and particle size, to storage at room temperature for at least 10 days.
- 14) A composition as claimed in any of claims 1 to 13 which is non-haemolytic up to a concentration of 0.2% total amphiphile.
- 15) A composition as claimed in any of claims 1 to 14 which is non-haemolytic up to a concentration of 1% total amphiphile.

- 29 -

- 16) A pharmaceutical formulation comprising at least one composition as claimed in any of claims 1 to 15 and at least one biologically tolerable carrier or excipient.
- 17) A kit suitable for establishing a biologically tolerable formulation of an active agent, said kit comprising at least one composition as claimed in any of claims 1 to 8